

## DETAILED ACTION

### *Allowable Subject Matter*

Claim 1 is allowed. The following is an examiner's statement of reasons for allowance:

Jang et al (KR 03-39872) discloses a beta-glucan isolated from *Aureobasidium pullulans* SM-2001 as set forth previously. The reference does not teach the treatment of osteoporosis. Ikewaki et al (US 2002/0082418) teaches therapeutic methods comprising the administration of a beta 1,3/1,6 glucan derived from *Aureobasidium*. The reference suggests treatment of various disorders, including osteoporosis. See paragraphs [0019]-[0021] and [0059]. The treatment of osteoporosis is not exemplified, and the therapeutic mechanism of this product appears to be the induction of a higher level of IL-6. See example 4 and Table 3. However, increased production of IL-6 is associated with bone *resorption*. See Chung et al (J. Hum. Genet., 2003) at the paragraph bridging pages 243 and 244 and Klecolt-Glaser et al (PNAS, 2003) at abstract. Therefore, one of ordinary skill would not have a reasonable expectation of success in using this agent for the treatment of osteoporosis.

Sorgente et al (US 2004/0058889) teaches the use of beta-glucan for the treatment of osteoporosis. The reference exemplifies a beta-glucan derived from yeast and notes that glucans derived from various sources can have "very different physical and biological properties." See paragraph [0012]. This, taken together with the teaching of Ikewaki above, would not provide one of ordinary skill with a reasonable expectation of success in administering the recited beta-glucan for the treatment of osteoporosis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:30 to 4:00 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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/Leigh C. Maier/  
Primary Examiner  
Art Unit 1623